K 124002

VARIAN
medical systems

# Premarket Notification [510(k)] Summary
## Verification Console

FEB 2 1 2013

The following information is provided following the format of 21 CFR 807.92.

**Submitter's Name:**

Varian Medical Systems, Inc.
3100 Hansen Way
Palo Alto, CA 94304

Contact Name: Peter Coronado
Phone: 650/424.6320
Fax: 650/842.5040
Date: December 2012

**Proprietary Name:**

Verification Console

**Classification Name:**

Medical charged-particle radiation therapy system
21 CFR 892.5050, Class II
Product Code: IYE

**Common/Usual Name:**

Verification Console

**Predicate Devices:**

Varian Treatment (K082416)

**Device Description:**

Verification Console is designed to perform an interface role to connect to proton therapy control systems.

The general function of the Verification Console is to allow treatment plans and images to be retrieved from the Varian Oncology Information System and sent to the device's treatment control system (TCS), planned treatment plan parameters to be verified against the TCS delivery parameters for accuracy, and treatment history to be recorded in the Varian Oncology Information System for use and display throughout ARIA and Eclipse. ARIA and Eclipse are separately cleared devices from Varian Medical System.

**Statement of Intended Use**

Verification Console is designed to assist the operator of a proton radiation therapy device. Verification Console retrieves treatment plans from an oncology information system (OIS) and sends plans to the treatment device's treatment control system (TCS). Verification Console then performs verification of treatment plan parameters against TCS delivery parameters for accuracy prior to beam authorization, and sends the treatment history for recording to the OIS.

Verification Console's statement of intended use was based on and is substantially equivalent to the intended use statement of Varian Treatment. The differences are minor, not critical to the intended

therapeutic use of the device, and do not affect the safety and effectiveness of the device when used as labeled since Verification Console's intended use statement is simply a more detailed account of the language in Varian Treatment's intended use statement.

**Technological Characteristics:** Verification Console is substantially equivalent to and has similar technological characteristics as the predicate device (Varian Treatment). The functionality of both devices is equivalent in safety and effectiveness.

The table below provides a comparison of the significant changes between Verification Console and Varian Treatment.

| Verification Console | Predicate - Varian Treatment |
|---|---|
| Supports proton beam delivery | Supports external beam photon delivery |
| Interface to Proton radiation therapy machine | Interface to non-Varian linac radiotherapy machines |

**Summary of performance testing:**

Results of verification and validation testing showed conformance to applicable requirements specifications and assured hazard safeguards functioned properly.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Mr. Peter Coronado
Director, Regulatory Affairs
Varian Medical Systems, Inc.
3100 Hansen Way, m/s E-110
PALO ALTO, CA 94304-1038

February 21, 2013

Re: K124002
Trade/Device Name: Verification Console
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: December 21, 2012
Received: December 26, 2012

Dear Mr. Coronado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris, Director
Division of Radiological Health
Office of In Vitro Diagnostic Devices
And Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K124002

Device Name: Verification Console

Indications for Use:

Verification Console is designed to assist the operator of a proton radiation therapy device. Verification Console retrieves treatment plans from an oncology information system (OIS) and sends plans to the treatment device's treatment control system (TCS). Verification Console then performs verification of treatment plan parameters against TCS delivery parameters for accuracy prior to beam authorization, and sends the treatment history for recording to the OIS.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael FDA O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K124002